K111959

FEB - 6 2012

B.

510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap Histoacryl and Histoacryl Blue Topical Skin Adhesive

July 7, 2011

COMPANY: Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com

TRADE NAME: Aesculap Histoacryl and Histoacryl Blue

COMMON NAME: Topical Skin Adhesive

CLASSIFICATION NAME: Tissue adhesive

REGULATION NUMBER: 878.4010

PRODUCT CODE: MPN

DEVICE DESCRIPTION

Histoacryl and Histoacryl Blue are sterile liquid topical skin adhesives composed of n-butyl-2-cyanoacrylate monomer. The two products are different in only one respect: Histoacryl is provided as a colorless liquid, and Histoacryl Blue is colored with the dye D&C Violet #2 with intent to ease visualization of the device during application. Histoacryl and Histoacryl Blue topical skin adhesives are supplied in 0.5 ml single patient use plastic ampoules. Each ampoule is sealed within a foil pouch so the exterior of the ampoule can remain sterile. Both tissue adhesives remain liquid until exposed to water or water-containing substances including tissue, after which it cures (polymerizes) and forms a film that bonds to the underlying surface.

INDICATIONS FOR USE

Histoacryl and Histoacryl Blue topical skin adhesives are intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl and Histoacryl Blue may be used in conjunction with, but not in place of, dermal sutures.

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Histoacryl and Histoacryl Blue Topical Skin Adhesive is substantially equivalent to Histoacryl and Histoacryl Blue Topical Skin Adhesive, Tissue Seal LLC (P050013). The only difference is the packaging.

PUPROSE FOR PREMARKET NOTIFICATION

The purpose of this submission is to gain marketing clearance for Histoacryl and Histoacryl Blue Topical Skin Adhesive.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Histoacryl and Histoacryl Blue Topical Skin Adhesive is equivalent in performance to the predicate device Histoacryl and Histoacryl Blue Topical Skin Adhesive, Tissue Seal LLC (P050013). The main difference between Histoacryl and Histoacryl Blue and the predicate device is the ampoule is sealed within an aluminum pouch.

PERFORMANCE DATA

Testing was performed in accordance to FDA's Class II Special Control Guidance Document for Tissue Adhesive for the Topical Approximation of Skin to demonstrate that that the Aesculap Histoacryl and Histoacryl Blue Topical Skin Adhesive is substantially equivalent to other predicate devices. The following testing was performed:

- Tensile strength (ASTM F2458-05)
- Set (polymerization) time
- Viscosity
- GC Chemical Analysis

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 6 2012

Aesculap, Inc.
% Ms. Kathy A. Racosky
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K111959
Trade/Device Name: Aesculap Histoacryl and Histoacryl Blue Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: February 02, 2012
Received: February 03, 2012

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K111959

Device Name: Aesculap Histoacryl and Histoacryl Blue Topical Skin Adhesive

Histoacryl and Histoacryl Blue topical skin adhesives are intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl and Histoacryl Blue may be used in conjunction with, but not in place of, dermal sutures.

Prescription Use ___X___ and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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